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October 12, 2001

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on HPV Test Plan and Robust Summaries for Tall Oil Fatty Acids and Related Substances

Dear Administrator Whitman:

The following comments on the test plan for "Tall Oil Fatty Acids and Related Substances" are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than nine million Americans. We again request a response from the Environmental Protection Agency (EPA) to these comments, as we have yet to receive a response to any of the 26 test plan comments we have submitted to date.

The Pine Chemicals Association, Inc.'s (PCA's) test plan is yet another example of a proposal of irrelevant and inappropriate tests. The plan violates the following terms of the October 1999 Agreement outlining principles to reduce repetitive or uninformative tests on animals:

1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.

2. Participants shall maximize the use of existing and scientifically adequate data to minimize further testing.

3. Participants shall maximize the use of scientifically appropriate categories of related chemicals and structure activity relationships.

8. In analyzing the adequacy of screening data for chemicals that are substances Generally Recognized as Safe (GRAS) for a particular use by the Food and Drug Administration (FDA), participants should consider all relevant and available information supporting the FDA's conclusions. Participants reviewing the adequacy of existing data for these chemicals should specifically consider whether the information available makes it unnecessary

to proceed with further testing involving animals. As with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant.

Our two main objections to this test plan are:

1. **The test plan does not reflect a thoughtful evaluation of the value of additional tests in providing hazard information on the fatty acids.**

2. **The PCA failed to coordinate with other industries to develop a comprehensive category of fatty acids and related substances.**

1. The test plan does not reflect a thoughtful evaluation of the value of additional tests in providing hazard information on the fatty acids.

The PCA's test plan calls for aquatic toxicity and *in vitro* genotoxicity tests on tall oil fatty acids. The PCA's claim that "no animal testing will be conducted" overlooks the fact that fish are indeed animals who will be killed if the proposed tests are carried out. We recommend that the PCA omit its aquatic toxicity tests on fish, as nonanimal test methods are available and the properties of the tall oil fatty acids make aquatic toxicity tests meaningless. In violation of principles 1, 2, and 8 of the October 1999 Agreement, the test plan fails to consider the relevance and value of these additional tests.

The tall oil fatty acids are composed mainly of palmitic acid, stearic acid, oleic acid, and linoleic acid, which are natural products derived from the pulping of pine trees. Tall oil fatty acids are characterized by low toxicity to animals and are found in many plant and animal tissues (including the fatty tissues of fish), many food products (such as olive oil and canola oil), as well as in personal care products such as soaps and lotions. Palmitic acid is the primary fat in meat and dairy products. Stearic acid is found in both animal and plant sources and is used as a flavoring agent. Oleic acid is the primary fatty acid in olive oil and canola oil and is also a component of the fatty tissues of fish. Linoleic acid is an essential fatty acid, the major component of corn oil and soybean oil, and also a component of the fatty tissues of fish. All of these chemicals are labeled "Generally Recognized as Safe (GRAS)" food additives by the Food and Drug Administration.

We strongly recommend that the consortia omit the acute fish toxicity test. It is entirely inappropriate to test components of fatty fish tissue on fish. Furthermore, nonanimal test methods are available for studying aquatic toxicity, such as tests with algae and the TETRATOX assay.

Moreover, the insolubility of the fatty acids hinders the ability to conduct aquatic tests. The PCA has decided against even attempting to determine the hydrolysis of the tall oil fatty acids, because their solubility in water is so low and they lack a functional group that would be susceptible to hydrolysis.

The PCA acknowledges the limitations of testing fatty acids in aquatic environments and therefore proposes to manipulate experimental conditions to enhance solubility. The PCA does not describe how it intends to alter the OECD test guidelines, but does raise the possibility that the experimental conditions themselves "may cause non-specific toxicological effects." This confounds the experimental results and leads to difficulty in interpretation. The relevance of those experimental results for predicting aquatic toxicity of fatty acids is highly questionable at best.

2. The PCA failed to coordinate with other industries to develop a comprehensive category of fatty acids and related substances.

The components of the tall oil fatty acids—palmitic acid, stearic acid, oleic acid, and linoleic acid—are also found in another category proposed by the PCA, "Tall Oil and Related Substances," posted on July 17, 1999. These two categories should be combined to reduce duplicative testing and maximize the use of structure activity relationships. A failure to do so is a clear violation of principle 3 of the October 1999 Agreement.

Moreover, these individual components of tall oil fatty acids (palmitic acid, stearic acid, oleic acid, and linoleic acid) are all being sponsored by the Soap and Detergent Association. Under the HPV framework and the October 1999 Agreement, these chemicals clearly should all be combined into one category. This test plan reflects a complete lack of inter-industry cooperation. The EPA must reject this test plan as scientifically inappropriate, and we reiterate our request to the EPA to inform us of how it intends to encourage better inter-industry collaboration and cooperation to eliminate repetitive tests.

Thank you for the opportunity to comment. I can be reached at 202-686-2210, ext. 302, or via e-mail at <ncardello@pcrm.org>. Correspondence should be sent to my attention at PCRM, 5100 Wisconsin Ave., N.W., Washington, DC 20016. I look forward to your response on these important issues.

Sincerely,

Nicole Cardello, M.H.S.
Staff Scientist